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EXAMINER

STAICOVICI, STEFAN

ART UNIT

PAPER NUMBER

1732

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

MF-L

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/724,007	KURK ET AL.
	Examiner Stefan Staicovici	Art Unit 1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 01 April 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) 12-28 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11 and 29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 28 November 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 4, 5.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11 and 29, drawn to a mandrel, classified in class 425, subclass 275.
  - II. Claims 12-28, drawn to a dip molding process, classified in class 264, subclass 138.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions Group I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as, electrostatic or vapor deposition of a polymeric material.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Peter S. Dardi, PhD on June 10, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11 and 29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Specification***

6. The abstract of the disclosure is objected to because legal phraseology such “disclosed” should be avoided. Correction is required. See MPEP § 608.01(b).

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: “Mandrel for Dip Coating a polymer Valve Prostheses”.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 5-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen *et al.* (US Patent No. 5,376,113).

Jansen *et al.* ('113) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a top flat surface (8) from said contoured surfaces (5), said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 1)

Regarding claim 2, Jansen *et al.* ('113) teach a mandrel (7) having three contoured surfaces (5) defined by three ridges and three scallop regions (6).

In regard to claims 5 and 6, Figure 1 of Jansen *et al.* ('113) teach that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 7, Jansen *et al.* ('113) teach a flat top surface (8).

Regarding claim 10, Jansen *et al.* ('113) teach that contoured surfaces (5) are on the outside of mandrel (7).

10. Claims 1, 8, 11 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce *et al.* (US Patent No. 4,364,127).

Pierce *et al.* ('127) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (32) having a plurality of ridges extending between contoured surfaces which form scallop regions (30) of said heart valve (14) (see Figures 1 and 6). Further, Pierce *et al.* ('127) teach a top surface (40) formed by shims (35) which define an edge separating the contoured surfaces (see Figures 10 and 11).

Regarding claim 8, Pierce *et al.* ('127) teach a top surface having both flat and curved portions (see Figures 1 and 9).

Regarding claim 11, Pierce *et al.* ('127) teach contoured surfaces on the inside of mandrel (32) (see Figures 1 and 6).

In regard to claim 29, Pierce *et al.* ('127) teach a closed configuration of the resulting heart valve such that contoured surfaces of adjacent leaflets form a common boundary (see Figure 11).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) in view of Moe *et al.* (US Patent No. 6,174,331 B1).

Jansen *et al.* ('113) teach the basic claimed mandrel as described above.

Regarding claims 3 and 4, Jansen *et al.* ('113) do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A). Further, it should be noted that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article. It is submitted that a dip mold used to make such a configuration includes a radius of curvature in

order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes an edge having a radius of curvature. Furthermore, it is submitted that the actual radius of curvature is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an optimum radius of curvature in the mandrel of Jansen *et al.* ('113) in view of r Moe *et al.* ('331) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading and also because a curved edge improved releasability of the molded article.

In regard to claim 9, Jansen *et al.* ('113) do not teach a dip molding mandrel having a protruding portion away from the edge. Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit an increased thickness at the edge (see col. 3, lines 50-60 and col. 6, lines 31-51). It is submitted that a dip mold used to make such a configuration includes a protruding portion away from the edge in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes a protruding portion away from the edge. Therefore, it would have been obvious for one of ordinary skill in the art to have provided a protruding portion away from the edge as taught by Moe *et al.* ('331) in the dip mold of Jansen *et al.* ('113) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-0396. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H. Silbaugh, can be reached at (703) 308-3829. The fax phone number for this Group is (703) 305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Stefan Staicovici, PhD



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June 16, 2002